

In The United States Court of Federal Claims

No. 13-483V
(Filed: January 25, 2017)
Reissued: March 22, 2017¹

TANISIA CUNNINGHAM,
legal guardian of G.C.F.,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

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* Vaccine case; Motion for Review; MMR
* vaccination; Standard of review; *Althen*;
* Failure to establish causation; Autism
* Spectrum Disorder; Autoimmunity; Motion
* for Review denied.
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OPINION

Clifford J. Shoemaker, Shoemaker, Gentry & Knickelbein, Vienna, VA, for petitioner.

Voris Johnson, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

SMITH, Senior Judge:

Petitioner, Tanisia Cunningham, as legal guardian of G.C.F., seeks review of a decision issued by Special Master George Hastings denying her petition for vaccine injury compensation. Petitioner brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 et seq. (2012), alleging that G.C.F.'s autism spectrum disorder ("ASD") was caused by the measles, mumps, and rubella ("MMR") vaccine that he received at his one year well-child visit. The Special Master denied compensation, finding that G.C.F.'s ASD was not caused by the vaccinations. *Cunningham v. Sec'y of Health & Human Servs.*, 2016 WL 4529530

¹ An unredacted version of this opinion was issued under seal on January 25, 2017. The parties were given an opportunity to propose redactions, but no such proposals were made.

(Fed. Cl. Spec. Mstr. Aug. 1, 2016) (*Cunningham*). Petitioner now moves for review of that decision. For the reasons that follow, the Court **DENIES** her motion.

I. BACKGROUND

A brief recitation of the facts provides necessary context.²

G.C.F. was born on March 26, 2011. He received checkups throughout 2011, all of which were routine and indicated that G.C.F. showed no sign of developmental issues. He also received his routine vaccinations throughout the year and no problems were reported.

On March 28, 2012, G.C.F. attended his twelve month well-child visit to the pediatrician. At that appointment, his parents reported that he “rocks self to sleep on knees and elbows” and “bangs his head on side of crib.” No other developmental irregularities were reported. He received another round of vaccines. On April 3, 2012, G.C.F.’s father reported that G.C.F. repeatedly banged his head against the wall of his crib and that he was “concerned about autism.” The pediatrician indicated that G.C.F.’s general behavior was “developmentally appropriate” but recommended a developmental pediatric evaluation and pediatric neurology consultation.

On Monday, July 2, 2012, G.C.F. received his MMR³ and varicella⁴ vaccinations at his fifteen-month well-child visit. He was still reportedly banging his head on hard surfaces. And would “hold[] his head in the middle of activities and start[] crying.” Four days later on July 16, 2012, G.C.F. returned to the pediatrician with a history of fever and continuous crying for two days. On July 7, he was admitted to St. Barnabas Medical Center with a runny nose, cough, congestion, and a fever of 99.9 degrees. He was released the next day with a final diagnosis of “croup,”⁵ which is a type of viral infection. On July 24, 2012, G.C.F. returned to the pediatrician

² As the basic facts here have not changed significantly, the Court’s recitation of the background facts here draws from the Special Master’s earlier opinion in *Cunningham*.

³ Measles, mumps, and rubella vaccine is “a combination of live attenuated measles, mumps, and rubella viruses, administered subcutaneously for simultaneous immunization against measles, mumps, and rubella in persons 12 months of age or older.” *Dorland’s Illustrated Medical Dictionary* 2016 (32 ed. 2012) (“*Dorland’s*”).

⁴ Varicella virus is “a live attenuated virus vaccine prepared for human herpesvirus 3 (varicella-zoster virus); administered subcutaneously for production of immunity to varicella. *Dorland’s* at 2017.

⁵ Croup is “a condition resulting from acute partial obstruction of the upper airway, seen mainly in infants and children; characteristics include resonant barking cough, hoarseness, and persistent stridor. It may be caused by a viral infection (usually a parainfluenza virus), a bacterial infection (usually *Staphylococcus aureus*, *Streptococcus pneumoniae*, or *Streptococcus pyogenes*), an allergy, a foreign body, or new growth.” *Dorland’s* at 435.

with a rash “all over [his] body.” At that point his parents reported that he had “not been doing too well since administration of MMR and varicella about 3 weeks ago.” The pediatrician determined that the rash was “probably related to a varicella vaccine adverse event.”

At eighteen months of age, G.C.F. received an initial neurodevelopmental evaluation from nurse practitioner, Mary Van Horn, on October 3, 2012. At that evaluation, G.C.F.’s parents reported that a number of concerns, including head-banging, severe tantrums, lack of pointing or gestures, nonspecific use of “Mama” and “Dada,” poor eye contact, lack of single words, repetitive use of toys, and inconsistent response to his name. Ms. Van Horn concluded that G.C.F. “should be considered at risk for autism,” and recommended a follow-up with Dr. Malia Beckwith, a developmental pediatrician.

On October 20, 2012, G.C.F. received an initial evaluation by the New Jersey Early Intervention System, in which he scored significantly below the mean in the “Personal/Social,” “Adaptive,” “Communication,” and “Cognitive” testing categories. On October 23, 2012, G.C.F. was evaluated for speech therapy at Children’s Specialized Hospital, at which it was determined that his expressive and receptive language skills showed that he was below the limits expected for his age in both categories, which confirmed a diagnosis of expressive/receptive language disorder. On January 22, 2013, at twenty-one months of age, Dr. Beckwith evaluated G.C.F. and reviewed his history, determining that G.C.F. met the criteria for an “autistic disorder.”⁶ G.C.F. was again evaluated by Dr. Beckwith on April 16, 2013, at which point she noted “no regression or loss of skills,” but her diagnostic impression continued to be “autistic disorder,” along with mixed expressive receptive language disorder, sensory integration concerns, and significant feeding rigidity.

Petitioner filed this vaccine petition on July 17, 2013, pursuant to the Vaccine Act and alleging that G.C.F. suffered a “brain injury” resulting from adverse reactions to one or more of many vaccinations administered between March 28, 2011 and July 2, 2012. *See* Petition (hereinafter “Pet,”) at 5. Petitioner filed the expert report and curriculum vitae of Dr. Yuval

⁶ Autistic disorder is “a severe pervasive developmental disorder with onset usually before three years of age and a biological basis related to neurologic or neurophysiologic factors; it is characterized by qualitative impairment in reciprocal social interaction (e.g. lack of awareness of the existence of feelings of others, failure to seek comfort at times of distress, lack of imitation), in verbal and nonverbal communication, and in capacity for symbolic play, and by restricted and unusual repertoire of activities and interests. Other characteristics sometimes include cognitive impairment, hyper- or hyporeactivity to certain stimuli, stereotypic behaviors, neurological abnormalities such as seizures or altered muscle tone, sleeping or eating pattern abnormalities, and severe behavioral problems. It is associated with several genetic conditions and pre- and perinatal risk factors.” *Dorland’s* at 549.

Shafir, M.D.,⁷ on July 15, 2014. Respondent filed an expert report from Dr. Max Wiznitzer, M.D.,⁸ on December 10, 2014.

An evidentiary hearing was held in Washington, D.C. on September 18, 2015. Between December 17, 2015 and March 7, 2016, Post-Hearing Briefs were filed. On August 1, 2016, Special Master Hastings issued a decision denying petitioner's claim and finding that petitioner was not entitled to compensation because she failed to provide preponderate evidence that the vaccinations G.C.F. received on July 2, 2012, caused or aggravated G.C.F.'s autism spectrum disorder. On August 31, 2016, petitioner filed a Motion for Review ("MFR") of the Special Master's decision. Respondent filed a response to petitioner's Motion for Review ("Resp. to

⁷ Dr. Shafir attended the Sacker School of Medicine in Tel Aviv, Israel, and graduated *magna cum laude* in 1982. Curriculum Vitae of Dr. Yval Shafir, Petitioner's Exhibit (hereinafter "Pet. Ex.") 15 at 1. After completing his residency in Israel, he continued as a pediatric resident at the North Shore University Hospital in New York from 1986-1988, followed by a pediatric neurology fellowship at Washington University in St. Louis from 1988-1991 and a pediatric neurophysiology and epileptology fellowship at Miami Children's Hospital. *Id.* He was certified by the American Board of Pediatrics, the American Board of Psychiatry and Neurology with a special qualification in Child Neurology, and the American Board of Clinical Neurophysiology, and he is licensed to practice medicine in Maryland. *Id.* at 2. Dr. Shafir currently practices as a pediatric neurologist in Baltimore, MD. *Id.* at 3. He has held a number of teaching positions since 1988, including assistant professor in neurology and pediatrics at the United Services University of the Health Sciences, F. Edward Herbert School of Medicine and assistant professor in the Department of Pediatrics at the University of Maryland School of Medicine. *Id.*

⁸ Dr. Wiznitzer received his B.S. in medical education in 1975 and his medical degree in 1977, both from Northwestern University. Curriculum Vitae of Dr. Max Wiznitzer, Respondent's Exhibit (hereinafter "Resp. Ex.") B at 1. He completed his residency in pediatrics in 1980 at the Children's Hospital Medical Center in Cincinnati, Ohio, followed by a one-year fellowship at the Cincinnati Center for Developmental Disorders, a three-year fellowship in pediatric neurology at the Children's Hospital of Philadelphia, and a two-year fellowship studying higher cortical functions at the Albert Einstein College of Medicine in New York. *Id.* at 1-2. He has been appointed to practice at a number of hospitals, most notably the Rainbow Babies and Children's Hospital in Cleveland. *Id.* at 2. At Rainbow Babies and Children's Hospital in Cleveland, Dr. Wiznitzer served as Co-Director of the Rainbow Autism Center in 1991, as the Chief of the Division of Pediatric Neurology from 1992-95, and as the Director of the Rainbow Autism Center from 1992-2010. *Id.* at 3. He is certified by the American Board of Pediatrics, the American Board of Psychiatry and Neurology with a special qualification in Child Neurology, and he maintains licenses to practice in Ohio, Pennsylvania, and New York. *Id.* at 5. He has taught pediatrics and neurology since 1986 at the Case Western Reserve University School of Medicine, and became Professor of Pediatrics in 2013. *Id.* at 2. In his current practice he estimates that approximately 1/4 of his patients have been diagnosed with autism. Transcript of Proceedings, Sept. 18, 2015, page 85 (hereinafter "Tr. ___").

MFR”) on September 29, 2016. Petitioner requested oral argument. However, due to the high quality and fully explanatory nature of the Motion for Review and Response, oral argument on this motion is deemed unnecessary. The Motion for Review is now ripe for decision.

II. DISCUSSION

Under the Vaccine Act, this Court may review a special master’s decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)-(2). In that instance, the Court may: “(A) uphold the findings of fact and conclusions of law..., (B) set aside any findings of fact or conclusion of law...found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law..., or, (C) remand the petition to the special master for further action in accordance with the court’s direction.” *Id.* at § 300aa-12(e)(2)(A)-(C). Findings of fact and discretionary rulings are reviewed under an “arbitrary and capricious” standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec’y of Health & Human Servs.*, 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992); *see also Doyle ex rel. Doyle v. Sec’y of Health & Human Servs.*, 92 Fed. Cl. 1, 5 (2010).

Althen provides the evidentiary burden for petitioner attempting to succeed in a vaccine petition based on causation. *See generally Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). In order to prove causation-in-fact, a petitioner must

show by preponderant evidence that the vaccination brought about [petitioner’s] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. at 1278. In order to succeed, petitioner must provide a “reputable medical or scientific explanation” for their claim. *Id.*

Within this framework, petitioner makes two numbered objections to the August 1, 2016 decision. *See* MFR at 2. First, she asserts that the Special Master erred in determining that G.C.F.’s head-banging prior to the vaccinations at issue was the onset of his autism and in so doing abused his discretion in denying G.C.F.’s claim on that basis. *Id.* Second, she alleges that the Special Master abused his discretion by conflating G.C.F.’s alleged injury (autoimmune⁹

⁹ Autoimmune means “characterized by a specific humoral or cell-mediated immune response against constituents of the body’s own tissues (self antigens or autoantigens).” *Dorland’s* at 181.

encephalopathy¹⁰ with sequelae¹¹ of autism) with *just* the sequelae of his injury and impermissibly raising the burden of proof. *Id.*

A. Onset

Petitioner argues that the Special Master erred in determining that G.C.F.'s head-banging indicates the onset of his autism and began prior to the vaccination at issue. In making this argument, petitioner points out that "while head-banging is present in a certain percentage of children with autism—it is not diagnostic of autism7[sic]." MFR at 9. Petitioner clearly misunderstands the connection Special Master Hastings has drawn between head-banging and autism.

Petitioner also points to medical literature to dispute the Special Master's findings, namely that one of the articles relied upon by Special Master Hastings states that "[s]tereotypies associated with ASDs often do not appear until after 3 years of age...." MFR at 10. Petitioner also focuses on the fact that Dr. Wiznitzer indicated that G.C.F.'s head-banging was not causing any physical harm to G.C.F. *Id.* Petitioner misconstrues this statement to mean that stereotypies that appear before the age of three or that are non-injurious could not possibly indicate autism.

While it is true that Special Master Hastings drew a connection between G.C.F.'s early head-banging and his autism diagnosis, nothing in the Special Master's opinion indicated that G.C.F.'s head-banging was dispositive of his diagnosis. In fact, as respondent pointed out, Special Master Hastings "specifically noted that...Dr. Wiznitzer did *not* claim that the head-banging alone is sufficient to diagnose (or predict that a child will develop) and ASD." Resp. to MFR at 11 (emphasis in original). However, Dr. Wiznitzer explained that "in *retrospect*, knowing as we do that G.C.F. in fact began exhibiting other clear-cut symptoms of autism later in 2012, he can state that the head-banging can be one of the stereotyped, repetitive behaviors that form a key part of autism." Dec. at 16 (emphasis in original) (citing Tr. 96). As the head-banging occurred when G.C.F. was 11 months old, and, as head-banging can retrospectively be an early warning sign for autism, it was entirely reasonable for Special Master Hastings to find that G.C.F. exhibited signs of autism prior to his MMR and varicella vaccines.

Petitioner's first numbered objection is, in reality, an objection to the analysis and weight awarded to the parties' expert testimony. Petitioner's argument centers on the desire for the Special Master to interpret the head-banging a different way. If this Court were to reassess the weight given to the expert testimonies, it would run afoul of the substantial deference given to Special Masters on review. Special Masters may use their discretion in weighing expert testimony, and case law supports that discretion. "The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Master's fact-intensive conclusions;

¹⁰ Encephalopathy is "a degenerative disease of the brain." *Dorland's* at 614.

¹¹ Sequela is "any lesion or affection following or caused by an attack of disease." *Dorland's* at 1696.

the standard of review is uniquely deferential for what is essentially a judicial process.” *Hodges v. Sec’y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). When a Special Master makes a finding based on the facts and evidence at issue, and when that finding is not irrational or implausible, this Court will not overturn that finding because a party dislikes the Special Master’s interpretation. As such, this Court must uphold the Special Master’s finding as to G.C.F.’s head-banging as not being arbitrary or capricious.

B. Burden of Proof

Petitioner argues that Special Master Hastings abused his discretion by conflating G.C.F.’s alleged injury (autoimmune encephalopathy with sequelae of autism) with just the sequelae of his injury and impermissibly raising the burden of proof. MFR at 11. Essentially, petitioner is attempting to separate this case from other vaccine-autism cases of its kind by creating a step between vaccination and the ultimate end result of autism that would allow for compensation where other cases have failed. Petitioner does this by alleging that G.C.F.’s MMR and varicella vaccinations caused an autoimmune encephalopathy, and that the encephalopathy in turn resulted in autistic symptoms. *Id.* The Special Master did not find this theory to be persuasive, and this Court agrees with that assessment.

The Special Master evaluated Dr. Shafrir’s theory of an autoimmunity-autism link and found it unpersuasive. Dec. at 23. Even Dr. Shafrir acknowledged that his own theory was speculative. Throughout his testimony, Dr. Shafrir referred to characteristics of his theory as “unprovable ‘assumptions.’” Tr. 39. Furthermore, Dr. Shafrir acknowledged that the theory positing that autism is an autoimmune disease is a new concept that lacks research and proof to support it. Tr. 61, 67. Even if there was a link between autoimmune encephalopathy and autism, Dr. Shafrir was unable to provide any evidence to support the necessary allegation that either the MMR or varicella vaccines can cause the autoimmune response necessary to this theory. Dec. at 29. Finally, even if Dr. Shafrir was able to provide persuasive proof that autoimmunity was linked to autism and that the MMR and/or varicella vaccinations were linked to autoimmunity, nothing in Dr. Shafrir’s testimony or the evidence provided by petitioner supports the conclusion that G.C.F. even suffered the necessary autoimmune response to support this theory. In fact, Dr. Shafrir acknowledged that “there was never any test performed in G.C.F.’s case that would demonstrate the autoimmune response that he has theorized.” *Id.* at 30; Tr. 39, 78.

Once again it is important to recognize that Special Masters may use their discretion in weighing expert testimony. Special Master Hastings evaluated both the theory proposed by Dr. Wiznitzer and the autoimmunity theory posited by Dr. Shafrir, and he determined that Dr. Wiznitzer’s theory was more persuasive and in line with respected medical opinion. In weighing that evidence and expert testimony, Special Master Hastings was acting well within the bounds of his discretion. Petitioner attempts to argue that, because she never alleged a direct link between the vaccines and autism, “this is not simply an autism case.” MFR at 13. However, petitioner does posit that the vaccines caused autoimmune encephalopathy, which in turn caused G.C.F.’s autism. Regardless of petitioner’s attempt to differentiate this case from other autism

cases by creating this second step, the Special Master rightfully classified this case as an autism case, and, in treating it as such, did not raise the petitioner's burden of proof.

III. CONCLUSION

This Court finds that petitioners have not met their burden of proof in alleging that G.C.F.'s vaccinations caused or significantly aggravated his autism. For the foregoing reasons, the court **DENIES** petitioner's motion for review.¹²

IT IS SO ORDERED.

s/ *Loren A. Smith*

Loren A. Smith,
Senior Judge

¹² This opinion shall be unsealed, as issued, after February 8, 2017, unless the parties, pursuant to Vaccine Rule 18(b), identify protected and/or privileged materials subject to redaction prior to that date. Said materials shall be identified with specificity, both in terms of the language to be redacted and the reasons therefor.